DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3601. Action to enjoin and restrain the interstate shipment of methyltestosterone tablets. U. S. v. Cecil S. Goldberg (Abbey Products Co.). Consent decree granting injunction. (Inj. No. 238.)

COMPLAINT FILED: October 23, 1951, Southern District of California, against Cecil S. Goldberg, trading as the Abbey Products Co., Los Angeles, Calif.

NATURE OF CHARGE: The defendant was engaged in introducing and delivering for introduction into interstate commerce quantities of *methyltestosterone tablets* labeled as "Abbeyettes—Brand of Crystalline Methyltestosterone U. S. P. Each tablet contains 2.5 mg. Methyltestosterone."

The tablets were alleged to be misbranded under Section 502 (a), in that the labeling of the tablets was false and misleading. The labeling represented, implied, and suggested that the tablets were efficacious for the relief of certain symptoms and disease conditions, namely, nervousness, lack of pep, sleeplessness, vague aches and pains, lack of endurance, and lack of vigor, and that such symptoms and conditions in adult males are due to male hormone deficiency. The tablets were not efficacious for the relief of such symptoms and conditions, and such symptoms and conditions are not due to hormone deficiency in male adults.

The tablets were alleged to be misbranded further under Section 502 (f) (1), in that the labeling did not bear adequate directions for use since adequate directions for use for such tablets by a layman for self-medication cannot be prepared because the existence of a hormone deficiency can be determined only by a physician; and the tablets were inherently dangerous and not safe and efficacious for use except under the supervision of a physician.

Further misbranding, Section 502 (f) (2), the labeling of the tablets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the users since the labeling failed to state that the presence of cancer of the prostate can be detected only by a physician; since it failed to state the symptoms of defects of spermatogenesis; and since it failed to bear warnings against unsafe duration of dosage in that it warned against continued use of the drug extending over more than six months, whereas continued use of the tablets in the dosage suggested in the labeling may inhibit spermatogenesis and cause sterility within a period of six months.

Further misbranding, Section 502 (j), the tablets were dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in the labeling since such use of the tablets may result in sterility and may accelerate the malignant growth of a cancer of the prostate gland. The portion of the labeling setting forth the dosage and the frequency of use of the tablets was as follows: "Suggested Dosage: For adult males only: 2 tablets twice each day before breakfast and upon retiring * * * Caution: Do not take more than the dosage recommended. Continued use extending over six months is to be avoided."

DISPOSITION: October 23, 1951. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce any male hormone drug, including testosterone, misbranded under Sections 502 (a), 502 (f) (1) and (2), and 502 (j).